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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,894	11/21/2003	Dominic Zichi	SML.10	1434

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EXAMINER	
GRUN, JAMES LESLIE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,894	ZICHI ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 21 November 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/30/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, "the amount" lacks antecedent basis.

In claim 5 and claims dependent thereupon, "the" dissociation constant and concentration lack antecedent basis.

In claim 7 and claims dependent thereupon, "the" dissociation constant and concentration lack antecedent basis.

In claim 9, "the saturation point" lacks antecedent basis.

In claim 10, "the" concentration, amount, and K_d lack antecedent basis.

In claim 11, "the nonspecific binding" lacks antecedent basis.

In claim 12, "the" effective concentration lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, and 9-12 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Graham et al. (US 4,743,542).

Graham et al. teach increasing the dynamic range of an immunoassay and forestalling the hook effect by addition of unlabeled ligand binding partners to a solution containing sample and labeled antibodies.

Claims 1, 2, 4, and 9-12 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Neumann et al. (US 6,184,042).

Neumann et al. teach extending the measuring range of an immunoassay and reducing the hook effect by addition of oligomeric labeled ligand binding partners to a solution containing sample.

Claims 1, 2, 4, and 9-12 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Piasio et al. (US 4,098,876).

Piasio et al. incubated sample with antibodies in solution before contacting the mixture with immobilized antibodies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 5-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Graham et al. (US 4,743,542) or Neumann et al. (US 6,184,042) or Piasio et al. (US 4,098,876), if necessary in light of applicant's disclosure.

The teachings of Graham et al. or Neumann et al. or Piasio et al. are as set forth previously in this Office action. However the dissociation constant and the relative concentration of the ligand binding partners could not be determined from the disclosures of the references. Inherently, the parameters fall within the ranges as claimed based on the shifts in the standard curves noted in the references. If not, in light of applicant's calculations, it would have been implicit to have adjusted the concentration of the ligand binding partner in solution to the ranges as claimed to provide a usable standard curve in the methods.

Claims 1 and 3-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin et al. (US 2002/0037506) in view of Graham et al. (US 4,743,542) or Neumann et al. (US 6,184,042).

Lin et al. teach that sandwich assays using aptamers are, as antibody-based assays, subject to the hook effect (see ¶¶ [0016] and [0059]). However, the reference does not teach methods to reduce the hook effect.

The teachings of Graham et al. or Neumann et al. are as set forth previously in this Office action.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have reduced the hook effect in aptamer-based sandwich assays as taught to occur in Lin et al. with the addition of unlabeled ligand binding partner, as taught in Graham et al., or oligomeric ligand binding partner, as taught in Neumann et al., as was well known in the art. One would have had a reasonable expectation that the known methods would successfully reduce the hook effect and increase the measuring range of the assay regardless of the nature of the ligand binding partner in view of the comparability of aptamer-based and antibody-based sandwich assays taught in Lin et al.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cragle et al. (US 4,595,661) teach adding labeled, immobilized, or soluble third antibodies of a lower affinity for antigen than the first and second antibodies to reduce the hook effect.

Kinzler et al. (Mol. Cell. Biol. 10: 634, 1990) reduced the amount of a first analyte (antibodies) capable of binding to an immobilized first capture reagent (Cro-β-galactosidase) by reaction with the capture reagent (see page 635, col. 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
September 25, 2006

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